IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Paul R. LESCH, JR.	Confirmation No.: 6851
Application No.: 09/692,123	Group Art Unit: 3763
Filing Date: October 20, 2000	Examiner: Christopher Koharski
For: MEDICAMENT CARTRIDGE AND INJECTION DEVICE	Atty. Docket No.: 88066-5700

DECLARATION UNDER 37 C.F.R. § 1.132 OF PAUL R. LESCH, JR.

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Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Sir:

I, Paul R. Lesch, Jr., hereby declare as follows:

1. I am a citizen of the United States, residing at 7944 Joseph Court, Lino Lakes, Minnesota, 55014.

2. I have a degree of BSME conferred from GMI Engineering & Management Institute (Kettering) in 1996. I have ten (10) years of professional experience in the design of medical delivery devices, including injection. I was employed by Antares Pharma, Inc., the assignee of the present application, from 1997 to 2005 as a Principal Product Development Engineer. My duties at Antares Pharma included participating in and overseeing the design and development of various drug delivery devices, including needle-free and needle-assisted jet-injectors. I am listed as an inventor in eight U.S. Patents relating to injection devices.

3. I have reviewed and am familiar with the present Application, the current Office Action mailed March 12, 2007, the Amendment field on September 12, 2007, and the references cited in the Office Action, including U.S. Patent No. 4,968,302 to Schluter et al. ("Schluter"), No. 4,258,713 to Wardlaw et al. ("Wardlaw"), and No.

5,865,799 to Tanaka et al. ("Tanaka"). I am making the following statements as one of ordinary skill in the art of medicament injectors in support of patentability of the claims in this application.

4. The Examiner's statement in the Office Action that the injectors of Schluter and Wardlaw contain structurally similar elements that meet the claim limitations and are capable of dispersing the medicament in the manner of a jet injector is incorrect. Schluter and Wardlaw are both directed to a type of injector that are well known as "automatic hypodermic injectors" or "autoinjectors" (*see* Schluter at 1:6-11 ("The invention relates to an automatic injection or hypodermic device . . . ."); Wardlaw at 2:25-28 (". . . there is shown in FIG. 1 an automatic hypodermic syringe . . . .")). Persons of ordinary skill in the art knew at the time of filing that an autoinjector is a traditional hypodermic injector that includes a mechanism for automating the driving of the injector, in a way that mimics a hypodermic-syringe injection that is powered by hand. Autoinjectors thus employ a relatively slow injection, typically lasting more than about five seconds, and deposit the injected medicament in the same manner as would a hand-powered hypodermic syringe: the medicament is deposited in a bolus at the tip of the needle due to the slow and low-powered flow of the medicament unless injected into a vessel, in which case the medicament is deposited locally and carried away with the local flow. The characteristics of this medicament delivery is very different from that provided by a jet injector.

5. An autoinjector is structurally and functionally different from a jet injector. A person having ordinary skill in the art would have understood a "jet injector" to be a particular class of injector that injects medicament by creating a high-speed jet of the medicament that is powerful enough to penetrate the tissue of the patient to a significant distance beyond the exit of the injector. Achieving such depth of penetration is not merely a matter of providing a more powerful energy source, but requires significant structural elements that are different from those of a hypodermic injector.

6. Specifically, a jet injector requires structural features that are different from those in autoinjectors, to provide a high-energy, high-pressure jet of medicament,

such as firing and trigger mechanisms to generate the short duration, high-power firing stroke to generate sufficient pressure to drive the fluid out in a sufficiently powerful jet. These features include, for instance, a substantially more powerful and faster energy source and firing mechanism to drive the plunger when the injector is fired with a sufficiently elevated force and speed to generate the jet, a carefully dimensioned and configured jet nozzle to efficiently form the high speed jet, as well as a significantly more robust medicament container and supporting structure to contain the elevated pressures and withstand the shock produced by the rapid and powerful firing of the jet injector. Because of the high speed and pressure requirements for jet injectors, they are not powered by pressing directly on a plunger by hand, and the firing mechanism thus does not mimic a hand-powered injector. A typical jet injector will apply a pressure within the medicament device that can be more than about 10 to 100 times the pressures imposed on the medicament in the chamber of an autoinjector or traditional hypodermic syringe.

7. One of ordinary skill in the art would have known at the time the present Application was filed that a jet injector can be needle-free or needle-assisted. Needle-free injectors eject the medicament in a sufficiently powerful jet to penetrate the exterior of the skin and penetrate further into the tissue to the desired injection site. Needle-assisted jet-injectors use a needle to make the initial penetration, and the jet is powerful enough to penetrate deeper into the tissue from the needle, instead of merely being deposited as a bolus at the tip. We have found that the characteristics of dispersion of the medicament into the tissue of the patient are also very different from during injection with an autoinjector, with the medicament typically being absorbed much faster by jet injection. An example of a needle-assisted jet injector is disclosed in U.S. Patent No. 6,056,716 to D'Antonio et al. ("D'Antonio"), which shows needle-assisted jet injectors (FIGS. 9C, 9E-9H), a needle-free jet injector (FIG. 9D), and a conventional hypodermic needle injector (FIG. 9A). As shown in D'Antonio, the needle-assisted jet injector is used to bypass hair from veterinary patients and has a needle with an orifice to jet a stream of medicament. The needle-assisted jet injector thus allows significantly deeper penetration into the tissue than the needle tip, as opposed to the injection from conventional hypodermic needle.

8. Claims 1, 17, 18, and 30 of the Application specifically recite a jet injector. Claim 5, which recites that the injecting tip is configured for insertion or is inserted into a patient who is receiving the injection, is also directed to a jet injector of needle-assisted type. In view of the disclosure in the Application and knowledge in the art, it is my opinion that one having ordinary skill in the art would have understood how to make the jet injector recited in the claims based on the specification.

9. Thus, based on the knowledge in the art, a person having ordinary skill in the art would understand that the present claims are directed to a jet injector device, and that such a device is significantly different from the autoinjectors of Schluter and Wardlaw. In my opinion, one of ordinary skill in the art would have found that Schluter and Wardlaw disclose autoinjectors, that Tanaka discloses a hand-operated pre-filled syringe, and that none of these references alone or in combination provides any teaching or suggestion or motivation to modify any of the disclosed devices to provide a jet injector.

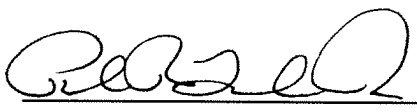
10. Further, the devices disclosed in Schluter, Wardlaw, and Tanaka are not readily modifiable to be jet injectors, pursuant to the recitations of claims 1, 17, 18, and 30, because of the significant structural requirements of a jet injector explained above. Compared to a hypodermic injector, a device configured for jet injection, as defined in claims 1, 17, 18, and 30, requires a significantly more robust medicament chamber and supporting structure to contain and withstand the elevated pressures and the shock produced by the rapid and powerful firing. It would not be a mere matter of strengthening the devices or providing bigger energy sources of these references to convert them to jet-inject the medicament. Additionally, producing a jet requires a careful combination of an energy source with the jet orifice, such as involving careful selection of a needle configuration, which would require more than routine optimization and design choice.

11. For example, Schluter requires a needle that one of ordinary skill in the art would understand is highly unlikely to be able to withstand the high pressures and shock of a sudden, high powered firing if it were used in jet injection. The Schluter needle has a winding body 310, 311, 312, which requires a slow injection to pierce both sealing elements. A fast, powerful firing would likely bend the winding body and possibly break the needle, and also cause the needle to become misaligned, so it would not reliably penetrate the seals or patient at a workable angle. Other features of Schluter make it apparent that its structure is unsuitable for jet injection, including the very thin lifting-sealing element (29), which one of ordinary skill in the art would find unlikely to resist high pressures of jet injection and more likely to release the seal under the pressure.

12. Similarly, in Wardlaw, the disclosure of the ferrule and foam column arrangement for holding the needle does not provide to one of ordinary skill in the art a teaching or suggestion of a structure sufficiently robust to be capable of withstanding the rigors of jet injection, and the structure likely would not maintain the proper positioning of the needle during a high-powered injection such as that used in the presently recited jet injection.

13. I further declare that all statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Dated this 3RD day of October, 2007.

Declarant: 

Paul R. Lesch, Jr.